

ASPIRIN- aspirin tablet
Richmond Pharmaceuticals, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ENTERIC COATED ASPIRIN 325mg

Active Ingredient

(in each tablet)

Aspirin 325 mg (NSAID) *

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/ Fever Reducer

Uses

temporarily relieves

- headache
- menstrual pain
- muscle pain
- toothache
- minor pain or arthritis
- pain and fever of colds

Warnings

Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early signs of Reye's syndrome, a rare but serious illness.

Allergy Alert: Aspirin may cause a severe allergic reaction which may include

- hives
- asthma (wheezing)
- shock
- facial swelling

Stomach Bleeding Warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood-thinning (anticoagulant) or steroid drug
- takes other drugs containing prescription or nonprescription NSAIDs (ibuprofen, naproxen, others)
- takes more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product.

Do not use

- if you have ever had an allergic reaction to any other pain reliever / fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout or arthritis
- taking any other drug
- under a doctor's care for any serious condition

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
 - pain gets worse or lasts more than 10 days
 - fever gets worse or lasts more than 3 days
 - redness or swelling is present in the painful area
 - any new symptoms appear
 - ringing in the ears or a loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

DRINK A FULL GLASS OF WATER WITH EACH DOSE

- **adults and children 12 years and over** : 1-2 tablets every 4 hours while symptoms last, but not more than 12 tablets in 24 hours.
- **Children under 12 years** : ask a doctor

Other Information

- avoid excessive heat or humidity
- store at 15-30 °C (59-86 °F)

Inactive Ingredients

croscarmellose sodium, D&C Yellow #10 (Al-Lake), FD&C yellow #6 (Al-Lake), HPMC, methacrylic acid copolymer, polyethylene glycol, propylene glycol, PVP, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide

Questions or Comments

Call 631-981-4600, 8.30am – 4.30 pm ET Monday-Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS

BROKEN OR MISSING

Manufactured by: Advance Pharmaceutical, Inc. Holtsville, NY 11742

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 54738-111-01....E/C Aspirin 325mg - 100tabs

*Compare to active ingredient in Ecotrin®

NDC 54738-111-01

See New Warnings Information

ENTERIC COATED Aspirin (NSAID)

325 mg

**Pain Reliever/
Fever Reducer**

100 TABLETS

Richmond Pharmaceuticals, Inc.

Drug Facts

Active ingredient (in each tablet) Purpose
Aspirin 325 mg (NSAID)Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses Temporarily relieves ■ headache ■ menstrual pain
■ minor pain of arthritis ■ muscle pain ■ toothache
■ pain and fever of colitis

Warnings
Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

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■ take other drugs containing prescription or nonprescription NSAIDs (ibuprofen, naproxen, or others)
■ take more or for a longer time than directed
■ have 3 or more alcoholic drinks every day while using this product

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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Distributed by: Richmond Pharmaceuticals, Inc.
Richmond, VA 23233, USA

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PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

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- taking any other drug

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■ children under 12 years: ask a doctor

Other information ■ avoid excessive heat or humidity
■ store at room temperature (15°-30°C (59°-86°F))

Inactive ingredients croscarmellose sodium, D&C yellow #10 (AI-lake), FD&C yellow #6 (AI-lake), HFMC, methacrylic acid copolymer, polyethylene glycol, propylene glycol, PVP, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide

Questions or comments?
call 800-270-4498, 8:30 am-4:30 pm ET, Monday - Friday

NDC: 54738-111-03....E/C Aspirin 325mg - 1000tabs

ASPIRIN		
aspirin tablet		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	ORAL	NDC:54738-111
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	AP;0 11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-111-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	
2	NDC:54738-111-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	05/01/2015	

Labeler - Richmond Pharmaceuticals, Inc (043569607)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-111)